

REMARKS

The Applicants would like to thank Examiner Jerry Cumberledge and Supervisory Examiner Eduardo Robert for providing an opportunity to discuss the present application during Examiner interviews on August 23, 2006 and December 12, 2006. A summary of the interviews in accordance with MPEP § 713.04 is set forth below in section 6.

The Office Action dated July 10, 2006 and cited references have been considered. Claims 1-44 are currently pending. Reconsideration and allowance are respectfully requested.

1. Drawing Objections

On pages 2-3 of the Office Action, the drawings were objected to for various informalities. In particular, the Examiner objected to Figures 15h, 15k and 26b for having multiple reference numerals referring to the same drawing element. Applicants have amended Figure 15h to change 93' to 93 for consistency with the specification. As discussed during the first Examiner interview, however, Applicants respectfully submit that the drawings, as explained by the specification, are sufficiently clear. For example, with respect to Figure 15h, the reference numeral 93 refers to one portion of the washer 90 shown in Figure 9 and the reference numeral 193 refers to the individual washer shown in Figure 15j and described in paragraph [0103]. Figure 15h and paragraph [0101] illustrate that both the portion 93 of washer 90 and the individual washer 193 can have a contact surface 106 configured to contact inclined surface 58 of bone screws 50. Thus, Figure 15h is merely showing a configuration that can be applied to both the portion 93 of washer 90 and/or to the individual washer 193.

With respect to Figure 15k, this figure shows an alternate embodiment of washers 193 and 195. In Figure 15k, washers 193' and 195' are the same as washers 193 and 195 except for aperture 191, which does not have a tapered countersink but rather has a semicircular countersink portion 192. *See* paragraph [0104]. Reference numeral 198' refers to the body portion corresponding to washer 195' and reference numeral 199' refers to the body portion corresponding to washer 193'. The reference numerals 198' and 199' in Figure 15k are merely showing that these body portions are used with washers 195' and 193', respectively (in the same manner as shown in Figures 15i and 15j for elements 193, 195, 198, 199).

With respect to Figure 26b, this figure shows a partial sectional view of the fixation plate assembly 30 at slots 32 or 35 with the retainer assembly 33 in the locked position. By

comparison, Figure 26a shows a partial sectional view of the fixation plate assembly 30 at hole 34 with the retainer assembly 33 in the locked position. In Figure 26b, the reference numerals 32, 35 indicate that this configuration can be applied to slot 32 and slot 35. *See Figure 9* (showing slots 32, 35 and hole 34); *See also* paragraph [0118]. In Figure 26b, the reference numerals 46, 47 refer to recesses 46, 47 of slots 32, 35. Reference numerals 78, 79 refer to bores 78, 79 in slots 35 and 32. *See Figure 21* (showing bore 78 of slot 35) and *Figure 23* (showing bore 79 of slot 32). Thus, Figure 26b is merely showing a configuration that can be applied to slots 32, 35 and corresponding recesses 46, 47 and corresponding bores 79, 78.

In light of the foregoing remarks, Applicants respectfully submit that the drawings and the specification provide a clear description of the relevant subject matter. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to the drawings.

2. Rejection under 35 U.S.C. § 112, ¶ 2

On page 3 of the Office Action, claim 9 was rejected under 35 U.S.C. § 112, ¶ 2, for insufficient antecedent basis with respect to the term “the threaded hole of the fixation plate.” Claim 9 has been amended to correct the antecedent basis issue identified by the Examiner. In particular, claim 9 has been amended to recite “a threaded hole of the fixation plate.” Claims 25 and 39 have been similarly amended. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112 are respectfully requested.

3. Rejection under 35 U.S.C. § 102(e)

On page 3 of the Office Action, claims 1-8, 10-24, 26-38 and 40-44 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,235,034 to Bray (hereinafter “Bray”). This rejection is respectfully traversed.

Bray discloses a bone plate that can be used for stabilizing adjacent vertebrae or holding two portions of a bone together, *e.g.*, a broken bone, while it heals. As shown in Figures 1 and 2, the Bray apparatus 10 includes a base plate 14 with two bone screw holes 18, two bone screws 16, a retaining plate 20, a set screw 22 and a set screw aperture 26. The bone screws 16 are screwed into different bones 12. The retaining plate 20 is secured to the base plate 14 to prevent the bone screws 16 from backing out from the base plate 14. *See Bray at col. 4, line 31 - col. 5, line 60.* Figure 6A of Bray illustrates another embodiment in which the base plate 14 includes a recess 32 defined by a raised structure 33 that surrounds all four sides of the retaining plate area.

Figure 6B of Bray illustrates another embodiment in which the base plate 14 includes a recess where the raised structure 33 is situated on two sides of the retaining plate area. Figure 7 of Bray illustrates yet another embodiment in which the base plate has raised ribs 33 which create a recess 32 for receiving the retaining plate 20. *See* Bray at col. 5, line 61 - col. 6, line 30.

During surgery, the bone plate 14 is placed over at least two different bones, and the bone screws 16 are screwed into each bone through the bone screw holes 18. Then, the retaining plate 20 is placed over the heads of the bone screws and fixedly attached to the base plate 14. *See* Bray at col. 2, lines 53-58.

a. Independent Claim 1

Claim 1 of the present application recites:

1. A bone plate assembly comprising:

a fixation plate having a longitudinal axis along said plate, a locking plate, and a bone fastener wherein the fixation plate can be fixed by at least said bone fastener to a bone, and

wherein the locking plate is secured to the fixation plate and is longitudinally adjustable along said longitudinal axis from a first position wherein the bone fastener can be fixed to said bone to a second position in which the bone fastener is locked into position by the locking plate.

As is evident from the Bray drawings and specification, Bray does not disclose or suggest a locking plate that “*is secured to the fixation plate and is longitudinally adjustable along said longitudinal axis*,” as recited in claim 1 (emphasis added). By contrast, the retaining plate 20 in Bray is simply screwed onto the base plate 14 and doesn’t move. When the retaining plate 20 is secured to the base plate 14, it is not longitudinally adjustable. Nor does the retaining plate 20 in Bray move longitudinally if the set screw 22 is partially screwed into the base plate 14. As shown clearly in Figures 2 and 5 of Bray, there is no “play” between the retaining plate 20 and the base plate 14 because the holes 24 and 26 are just large enough to receive the set screw 22. Furthermore, when the retaining plate 20 is detached from the base plate 14, wherein the Office Action contends that it is longitudinally adjustable, the retaining plate 20 is clearly not “secured to the fixation plate,” as recited in claim 1.

Applicants appreciate the fact that, during proceedings at the U.S. Patent and Trademark office, claims are given their broadest *reasonable* construction *consistent with the specification*. Under its broadest reasonable construction, claim 1 indicates that the locking plate is secured to

the fixation plate and, at the same time, is longitudinally adjustable along the longitudinal axis of the fixation plate. Indeed, it would be antithetical to the principles of the invention, and therefore not *consistent with the specification*, to construe the claim otherwise, as it is important that the locking plate not be detachable from the fixation plate in use. This feature is not disclosed or suggested in Bray. This feature can provide the significant advantage that the bone plate assembly can be placed into the patient with the locking plate already secured to the fixation plate so that it is not freestanding, but can also be easily slid longitudinally to the locked position by the surgeon after the bone screws are set to prevent screw backout. This feature is shown clearly in Applicants Figures 1, 8 and 9, for example.

Applicants appreciate the allegation in the Office Action that Bray discloses that “the locking plate is *capable of being secured* to the fixation plate and is longitudinally adjustable” *See* Office Action at p. 4, lines 6-7 (emphasis added). But that is not what claim 1 recites. Claim 1 recites that “the locking plate *is secured* to the fixation plate.” Once the Bray retaining plate 20 *is secured* to the base plate 14, it is not longitudinally adjustable.

Very recently, the Federal Circuit addressed this exact issue in *Ormco Corp. v. Align Technology Inc.*, 79 USPQ2d 1931, 1937 (Fed. Cir. 2006). In particular, the court had to construe a claim to a medical device reciting “(a) three or more appliances with geometries selected to progressively reposition teeth, (b) instructions regarding order of use, and (c) a single package for provision of the appliances to the patient.” When the argument was made, as it has been here, that the phrase “and (c) a single package for provision of the appliances to the patient” only required that the devices be “capable of” being provided to the patient in a single package, the court rejected that argument:

We reject the district court’s conclusion that the “single package” limitation of claim 1 of the ‘611 patent merely requires that devices be ‘capable of’ being provided to the patient in a single package. Here, the claims are written to require that the devices actually be in a single “package.” In similar contexts, our cases have rejected claim constructions that would merely require that infringing devices be capable of being modified to conform to a specified claim limitation. *Id.*

As the old doctrine goes, that which infringes if later, anticipates if earlier. Accordingly, just as a device “capable of” being modified to conform to the single-package limitation could not

infringe the claim in *Ormco*, the fact that the locking plate of the prior art is “capable of being secured” when it is longitudinally adjustable is not an anticipation. Therefore, Bray cannot anticipate claim 1.

b. Independent Claim 15

Claim 15 of the present application recites:

15. An implant for the spine, comprising:
a plate for stabilizing the spine, the plate having a number of openings;
a number of bone anchorage screws each operable to engage a corresponding one of the openings of the plate; and
means for blocking the screws including at least one slide mounted on the plate to selectively cover at least a part of at least one of the screws and means for retaining the slide on at least one of the screws, the slide cooperating with the retaining means.

Bray does not disclose or suggest “at least one slide mounted on the plate to selectively cover at least a part of at least one of the screws,” as recited in claim 15. First, Bray does not disclose or suggest a slide mounted on the plate. As shown in Applicants’ specification, the slide 522 is mounted on the on the plate 501 (*see* Figure 1), the slide 90 is mounted on the plate 31 (*see* Figure 8), and they both slide while they are mounted on the plate. By contrast, the Bray retaining plate 20 is not a slide. Once it is mounted on the plate it does not slide. The Bray retaining plate 20 is simply screwed into the base plate 14 and it stays in that position.

Second, the Bray retaining plate 20 is not a slide mounted on the plate that “selectively cover[s]” at least a part of at least one of the screws, as recited in claim 1. In Applicants’ specification, the slide 522 selective covers the bone screws 515 and the slide 90 selectively covers the bone screws 50, in each case by moving from a first longitudinal position to a second longitudinal position. In Bray, by contrast, the retaining plate 20, when it is mounted on the base plate 14, simply covers the bone screws 16. It does not selectively cover them. It just covers them.

For the foregoing reasons, Applicants respectfully submit that Bray cannot anticipate claim 15. Accordingly, reconsideration and withdrawal of the rejection of claim 15 are respectfully requested.

c. Independent Claims 17 and 31

Independent claims 17 and 31 are identical to independent claim 1, except that claim 17 recites a “washer” instead of a “locking plate” and claim 31 recites a “retainer mechanism”

instead of a “locking plate.” The reasons set forth above as to why Bray does not anticipate claim 1 apply equally to claims 17 and 31. Accordingly, reconsideration and withdrawal of the rejection of claims 17 and 31 in view of Bray are respectfully requested.

d. Dependent Claims

Dependent claims 2-8, 10-14, 16, 18-24, 26-30, 32-38 and 40-44 depend from and include the recitations of one of the independent claims 1, 15, 17 or 31. These dependent claims are therefore believed to be allowable for at least the same reasons that the independent claims are allowable. In addition, the dependent claims recite additional features that further distinguish Applicants’ claims from Bray. For example, claim 2 recites that “said locking plate has only limited vertical and longitudinal freedom relative to the fixation plate.” In Bray, even when the set screw 22 is partially screwed into the base plate 14, the retaining plate 20 has *no* longitudinal freedom relative to the base plate 14. In other words, even if the independent claims were read as not requiring simultaneous fixation and longitudinal adjustability of the locking plate to the fixation plate, claim 2 would further define over Bray because (a) when the screw is not in place it does not provide “limited” longitudinal freedom (rather the locking plate has unlimited longitudinal freedom) and (b) when the screw is in place, even partially, it provides no longitudinal freedom. In other words, no matter how the system of Bray is used, and no matter what the stage of use in Bray, Bray never provides *limited* longitudinal *freedom* but rather provides either *unlimited* longitudinal freedom or *no freedom* whatsoever (as opposed to limited freedom).

As another example, claim 6 recites that “said opening in said locking plate is a slot having a first end opposing a second end which together define the longitudinal play of the locking plate relative to the fixation plate,” which is not disclosed or suggested by Bray.

In view of the above remarks, reconsideration and withdrawal of the rejection of dependent claims 2-8, 10-14, 16, 18-24, 26-30, 32-38 and 40-44 are respectfully requested.

4. Rejection under 35 U.S.C. § 103(a)

On page 7 of the Office Action, claims 9, 25 and 39 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bray in view of U.S. Patent No. 5,601,553 to Trebing et al. (hereinafter “Trebing”). The Examiner cites Trebing as allegedly disclosing a locking plate having a threaded bore. *See* Office Action at 7. In response to this rejection,

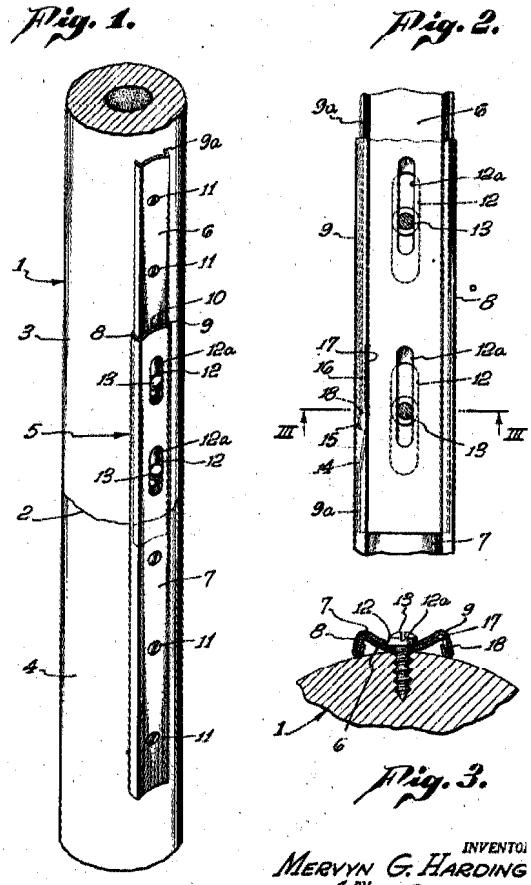
Applicants respectfully submit that Trebing cannot remedy the deficiencies of Bray discussed above. For example, Trebing does not disclose or suggest a fixation plate and a locking plate having the structural relationship recited in Applicants' independent claims, because Trebing only discloses a single plate. *See, e.g.*, Trebing Figures 1, 8 and 9. Therefore, the combination of Trebing and Bray cannot possibly produce Applicants' claimed invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are respectfully requested.

5. Related Applications

a. U.S. Application No. 10/134,463

As discussed during the Examiner interviews, Applicants filed a closely related application, U.S. Application No. 10/134,463 (hereinafter "the '463 Application") that has many of the same claims as the present application. The '463 Application is currently abandoned. Prior to abandonment, the USPTO issued an Office Action dated March 24, 2006. In the March 24, 2006 Office Action, the claims were rejected as allegedly being anticipated by U.S. Patent No. 2,406,832 to Hardinge (hereinafter "Hardinge") and by U.S. Patent No. 3,693,616 to Roaf et al. (hereinafter "Roaf"). A copy of the March 24, 2006 Office Action is submitted herewith.

Hardinge does not disclose or suggest a "locking plate [that] is secured to the fixation plate and is longitudinally adjustable along said longitudinal axis from a first position wherein the bone fastener can be fixed to said bone to a second position in which the bone fastener is locked into position by the locking plate," as recited in claim 1.



As shown in Figure 1 of Hardinge, there are two strips, an inner strip 6 and an outer strip 7 that slidably engage each other. Screws 11 anchor the strips to the bone. The outer strip 7 is also provided with a slot 12 which is wide enough to permit the head of the screw 13 to pass through it, whereas the inner strip 6 is provided with a slot 12a which permits only passage of the screw shaft..

The Examiner has proposed that if the inner strip 6 is viewed as the claimed fixation plate and the outer strip 7 is viewed as the locking plate, then it is possible that the locking plate 7 could slide longitudinally to cover either the screws 13 or the screws 11, thereby achieving the locking function as claimed. However, neither scenario is plausible under Hardinge's teaching. As for the covering the screws 13, it will be appreciated from Figure 3 that the outer strip 7 is at a level below that of the head of the screw 13, thereby preventing the outer strip 7 from overlaying the screw 13 and locking it. As for the screws 11, it will be appreciated that the

screw head 13 prevents the outer strip 7 moving to a position where it would even be possible to cover screw 11.

Furthermore, even to the extent it were at all possible to slide the outer strip 7 to a position where it overlays one of the bone screws, such arrangement would not meet the requirement of the claim recitation that the locking plate is adjustable “to a second position in which the bone fastener is locked into position by the locking plate.” More particularly, as discussed during the interview, the structure of Hardinge is, by design, one that does not lock the sliding member 7 in place relative to the member 6. Consequently, because the member 7 is not locked in place, the underling bone screw cannot be locked into position by the locking plate. In this regard, applicants refer the Examiner to column 1, lines 28-33, which states that it is an object of the invention to provide a fracture plate which “will automatically become shortened across the fracture line in the event that any adsorption at the fracture line takes place.” Applicants would submit that a device which, by design, moves as a bone heals is not one that by any reasonable construction can be said to be locked in place or lock a bone fastener into a position.

In sum, Hardinge cannot anticipate the invention because (1) the outer strip 7 cannot physically be moved to a position where it overlays either the bone screws 11 or the bone screws 13 and (2) even if the outer strip 7 could be so moved, it would not lock in such overlay position because, by design, the outer strip 7 is meant to move as the bone heals.

Roaf does not disclose or suggest a locking plate that is longitudinally adjustable along the longitudinal axis of the fixation plate, as recited in claim 1. By contrast, Roaf discloses cover plates 17 that are simply screwed into bars 1, 3 with screws 15. Once the cover plates 17 are screwed onto the bars 1, 3, they do not move. Thus, the cover plates 17 are not longitudinally adjustable along the longitudinal axis of the bars 1, 3. For at least these reasons, Roaf cannot anticipate claim 1 of the present application. It is noted, with appreciation, that the Examiners indicated during the interview that they were in agreement that the Roaf teaching does not anticipate the claimed invention.

Independent claims 17 and 31 of the present application are allowable over Hardinge and Roaf for substantially the same reasons as discussed above with respect to claim 1.

With respect to claim 15 of the present application, Hardinge does not disclose or suggest “means for blocking the screws” or “means for retaining the slide on at least one of the screws,” as recited in claim 15. As discussed above, the plate 7 in Hardinge does not and can not cover either the screws 13 or the screws 11. Therefore, Hardinge cannot anticipate claim 15. Roaf does not anticipate claim 15 because Roaf does not disclose or suggest “a number of bone anchorage screws” or “at least one slide mounted on the plate” or “means for retaining the slide on at least one of the screws,” as recited in claim 15.

For at least the foregoing reasons, the pending claims in the present application are allowable over Hardinge and Roaf.

b. U.S. Application No. 11/534,406

The Applicants filed U.S. Application No. 11/534,406 (“the ‘406 Application”) on September 22, 2006. The ‘406 Application is a continuation of the ‘463 Application. The ‘406 Application has a single claim 94 and that claim does not interfere with U.S. Patent No. 6,224,602, which is the subject of the Request for Declaration of Interference filed in the present application.

c. U.S. Application No. 10/693,604

Applicants also filed another closely related application, U.S. Application No. 10/693,604 (hereinafter “the ‘604 Application”) that has some of the same claims as the present application. The USPTO issued an Office Action dated October 11, 2006 in the ‘604 Application. In that Office Action, claims 13 and 14, which are identical to claims 15 and 16 of the present application, were rejected as allegedly being anticipated by U.S. Patent No. 2,486,303 to Longfellow (hereinafter “Longfellow”). A copy of the October 11, 2006 Office Action is submitted herewith.

Longfellow does not anticipate claim 15 of the present application because Longfellow does not disclose or suggest “means for blocking the screws” or “means for retaining the slide on at least one of the screws,” as recited in claim 15. In Longfellow, the plates A and B are specifically designed *to allow axial movement* between them after they have been installed and are in use. *See, e.g.*, Longfellow at col. 4, lines 11-13 (“the flanged portions of said plates [have] telescopic free longitudinal movement relative to each other”). Even if, as shown in Figure 5 of Longfellow, plate A is initially positioned to partially cover a bone screw in plate B,

the plates A and B are specifically designed to be able to move apart after installation so that the bone screw in plate B would no longer be covered. There is no mechanism in Longfellow for maintaining the plate A over the bone screw in plate B, and in fact, the plates are designed to allow axial separation after installation. *See* Longfellow at col. 2, lines 49-52 (“[R]elative axial movement of the apposed fragments, under the urge of the growth of callous between their abutting ends, is permitted.”). Accordingly, the plate A in Longfellow is not a “means for blocking the screws,” nor is there a “means for retaining the slide on at least one of the screws” in Longfellow. In the present application, by contrast, the slide is prevented from moving in any direction once it is engaged to cover a screw. For the foregoing reasons, Applicants respectfully submit that Longfellow cannot anticipate independent claim 15.

Although independent claim 1 has not been rejected as anticipated by Longfellow, Applicants note for completeness that Longfellow does not anticipate claim 1 of the present application. For example, Longfellow does not disclose or suggest a “locking plate” which “[locks] into position” a bone fastener, as recited in claim 1. As discussed above, even if, as shown in Figure 5 of Longfellow, plate A is initially positioned to partially cover a bone screw in plate B, the plates A and B are specifically designed to be able to move apart after installation so that the bone screw in plate B would no longer be covered. There is no mechanism in Longfellow for locking the plate A over the bone screw in plate B, and in fact, the plates are designed to allow axial separation after installation. Thus, Longfellow does not disclose or suggest “a longing plate” that “[locks] into position” a bone fastener, as recited in claim 1. The remaining independent claims 17 and 31 contain similar recitations and are also allowable over Longfellow. For example, claim 17 recites a washer that “[locks] into position” the bone fastener, and claim 31 recites a retainer mechanism that “[locks] into position” the bone fastener.

In sum, applicants submit that a prior art teaching of Longfellow which, by its very design, is intended to provide a device where a plates remain in slidable relation to one another cannot possibly meet the claims of the invention which require that a bone screw be “locked” into position. For at least the foregoing reasons, the pending claims in the present application are allowable over Longfellow.

6. Summary of Examiner Interviews

a. August 23, 2006 Interview

In accordance with MPEP § 713.04, Applicants provide the following summary of the Examiner interview conducted on August 23, 2006.

- (A) Exhibit. Not applicable.
- (B) Claims Discussed. 1-44.
- (C) Prior Art. U.S. Patent No. 6,235,034 to Bray and U.S. Patent No. 5,601,553 to Trebing et al.
- (D) Proposed Amendments. See above amendment to claims 9, 25 and 39.
- (E) Arguments. Please refer to the remarks and arguments set forth above.
- (F) Other Pertinent Matters. None.
- (G) Results or Outcome of Interview. Agreement with respect to the claims was not reached. The Examiners agreed to further consider Applicants' remarks submitted in this Amendment.
- (H) Interview by Electronic Mail. Not applicable.

b. December 12, 2006 Interview

In accordance with MPEP § 713.04, Applicants provide the following summary of the Examiner interview conducted on December 12, 2006.

- (A) Exhibit. Not applicable.
- (B) Claims Discussed. 13-14.
- (C) Prior Art. U.S. Patent No. 2,486,303 to Longfellow, U.S. Patent No. 2,406,832 to Hardinge, and U.S. Patent No. 3,693,616 To Roaf et al.
- (D) Proposed Amendments. Not applicable.
- (E) Arguments. Please refer to the remarks and arguments set forth above.
- (F) Other Pertinent Matters. None.
- (G) Results or Outcome of Interview. The Examiners agreed to further consider Applicants' remarks submitted in this Amendment.
- (H) Interview by Electronic Mail. Not applicable.

7. Conclusion

Having addressed all of the outstanding rejections of record, Applicants respectfully submit that the present application is in condition for allowance and notice to that effect is respectfully solicited. If there are any questions regarding this Amendment or the application in general, the Examiner is encouraged to contact the undersigned to expedite prosecution.

As a final matter, applicants make reference to the Suggestion of Interference filed previously and respectfully request that, should one or more of the claims be deemed in condition for allowance, that the application be placed into interference. As the present application includes claims literally copied from U.S. Patent No. 6,224,602, there is no question of interference-in-fact. Furthermore, as applicants copied the claims within the one-year date of the issuance of the patent, there is no issue arising under the one-year copying requirement of 35 U.S.C. §135(b). Nor is there a question of written description support for the copied claims. Finally, because applicants have an earlier effective filing date, there is at least *prima facie* entitlement to priority. Accordingly, all the threshold requirements of an interference having been satisfied, applicants respectfully request entry of this application into an interference. Applicants are at the Examiner's disposal to address any questions or concerns relating to the placement of this application into interference, and are willing to meet with the Examiner and a Special Programs Examiner to discuss initiation of an interference to the extent the Examiner believes it would be helpful.

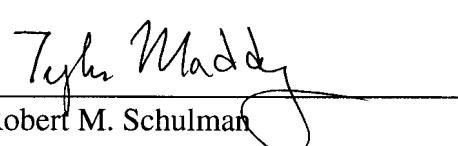
Applicants are submitting herewith a Petition for a 3-Month Extension of Time and a Charge Authorization for the required extension of time fee. No other fees are believed to be due with the filing of this Amendment. However, the Director is hereby authorized to treat any current or future reply requiring a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. Applicants also authorize the Director to charge any additional required fees, or to credit any overpayment, to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: DEC. 22, 2006

By:



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